# GOVERNMENT OF INDIA
# HEALTH AND FAMILY WELFARE
# LOK SABHA

UNSTARRED QUESTION NO:4672
ANSWERED ON:18.04.2001
VISIT OF DCGI & DG HEALTH TO PHARMACEUTICAL COMPANY
BALIRAM;P.R. KHUTE

**Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:**

(a) whether DCGI & DG Health have visited Pharma companies together for favours;

(b) whether it is also a fact that DCGI has granted permission for marketing of the new drug CLOPIDOGRIL within three days submission of trial report;

(c) whether Government are aware that DCGI has taken special favours from the company for granting the approval;

(d) the names of the new drugs cleared during 2000 and time taken to grant first approval after submission of clinical trial reports for each drug;

(e) if so, the details thereof;

(f) whether Ministry would like to refer the case to CBI; and
(g) if not, the reasons therefor?

## Answer

THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND FAMILY WELFARE (SHRI A. RAJA)

(a) No, Sir.

(b) No, Sir. The application for state III trials and approval of this drug was received on 5.7.2000 from M/s Torrent Pharmaceutical Ltd., Ahmedabad which has been granted permission to manufacture and market the drug. The firm was granted permission to conduct clinical trial and laboratory testing for quality from the Central Drug Laboratory, Calcutta on 3.10.2000.
Based on the results of the trials, which was received on 5.1.2001, results of tests conducted by Central Drug Laboratory received on 4.12.2000, recommendation of the experts and the evaluation of the clinical data, the approval to manufacture and market Clopidogrel was granted to M/s Torrent Pharmaceutical Ltd., on 1.2.2001.

(c) No, Sir.

(d) A list of New Drugs cleared during the year 2000, along with date of first approval granted and date of submission of clinical trail reports is annexed.

(e), (f) & (g) Do not arise in view of replies to part (a), (b) & (c) of the question.

ANNEXURE

NEW DRUGS APPROVED BY DRUG CONTROLLER GENERAL (INDIA) DURING THE PERIOD JANUARY 2000 TO DEC 2000

| Sl. NO. | NAME OF DRUG | CATEGORY | DATE OF C/T RECD. ON | COMMENT REPORTS RECD. ON | APPROVAL |
|---|---|---|---|---|---|
| 1. | OXICONAZOLE | ANTIFUNGAL | 03/05/1999 | 17/01/2000 | 07/12/1999 |
| 2. | +TEMOZOLAMIDE | ANTI CANCER | | 17/01/2000 | |
| 3. | OLANZAPINE | ANTI PSYCHOTIC | | 04/11/1999 | 27/01/2000 |

4. FLUVOXAMINE MALEATE ANTI DEPRESSANT 07/01/2000 21/02/2000

5. CELECOXIB NSAID 18/01/2000 22/02/2000
6.+NEVIRAPINE ANTI HIV 06/03/2000 -

7 REPAGLINIDE ANTI DIABETIC 09/10/1999 23/03/2000 09/03/2000

8.+ GANCICLOVIR ANTI VIRAL 05/04/2000 -

9.+TRAPIDIL ADJUNCT IN ANGIOPLASTY 11/05/2000
10. ROFECOXIB NSAID 14/06/2000 26/06/2000
11. ROSIGLITAZONE MALEATE ANTI DIABETIC 13/06/2000 28/06/2000
12. IRBESARTAN ANTI HYPERTENSIVE 17/05/2000 26/06/2000
13. GRANISETRON ANTIEMETIC 02/05/2000 05/07/2000
14.+ RITUXIMAB ANTI CANCER 10/07/2000
15.+ TRASTUZUMAB ANTI CANCER 10/07/2000
16. MOCLOBEMIDE ANTI DEPRESSANT 26/06/2000 28/07/200
17. CANDESARTAN ANTI HYPERTENSIVE 28/07/2000 31/08/200
18. VENLAFAXINE HCL ANTI DEPRESSANT 24/08/2000 18/9/2000
19. PAROXETINE HCL ANTI DEPRESSANT 25/08/2000 04/10/2000
20.+ IOMEPROL CONTRAST MEDIUM 05/10/2000
21.+ CAPECITABINE ANTI CANCER 12/10/2000
22.+ DACLIZUMAB IMMUNO SUPERSSIVE AGENT 12/10/2000
23.+ DIDANOSINE ANTI-HIV 15/10/2000
24. PIOGLITAZONE HCL ANTI DIABETIC 29/08/2000 17/10/2000
25. OCTY LONIUM FOR BROMIDE I.B.S. (IRRITABLE 11/09/2000 15/12/2000
BOWEL SYNDROME)
26. PARVASTATIN LIPID LOWERING AGENT 19/09/2000 20/12/2000 04/12/2000

+ Marked drugs mentioned above are either anti cancer/anti Aids or immuno suppressive agent which are life saving drugs and it is also difficult to conduct clinical trials with such drugs because of ethical reasons. Therefore these drugs are approved on the bassis of recommendations of experts.